

DRAFT Agenda
Pediatric Advisory Committee Meeting
November 16, 2006

Advisory Committee Conference Room, Room 1066
5630 Fishers Lane, Rockville, Maryland

Adverse Event Reporting as per Section 17 BPCA

8:00	Welcome and Introductory Remarks	Marsha Rappley, MD, Chair Dean, College of Human Medicine Michigan State University Carlos Peña, PhD, MS Executive Secretary, Office of Science and Health Coordination FDA, OC
8:10	Meeting Overview	Dianne Murphy, MD Director, Office of Pediatric Therapeutics FDA, OC
8:20	Committee Role in BPCA Safety Reviews	Rosemary Johann-Liang, MD, FAAP Deputy Director, Division of Drug Risk Evaluation CDER
8:30	Zyvox (linezolid)	Alan Shapiro, MD, PhD, FAAP Medical Officer, Pediatric and Maternal Health Staff CDER
8:50	Avandia (rosiglitazone)	Lisa Mathis, MD Director, Pediatric and Maternal Health Staff CDER
9:05	Zofran (ondansetron)	Felicia Collins, MD, MPH, FAAP Medical Officer, Pediatric and Maternal Health Staff CDER

Discussion and Q&As

<p>9:30 Celexa (citalopram) – Safety Update</p> <p>Review Update: QT Prolongation With Citalopram and Escitalopram</p> <p><i>Discussion and Q&As</i></p> <p>10:05 Break</p> <p>10:25 Trileptal (oxcarbazepine)</p> <p>Suicidality and Antiepileptic Drugs: Status of Clinical Trial Data Analysis</p> <p><i>Discussions and Q&As</i></p> <p>11:25 Tamiflu (oseltamivir) – Safety Update</p> <p><i>Discussion and Q&As</i></p> <p>12:15 Lunch</p> <p>1:30 Open Public Hearing</p> <p>2:30 Update on Current FDA Labeling Initiatives</p> <p><i>Discussion and Q&As</i></p> <p>3:10 Norvir (ritonavir)</p> <p>3:25 Rapamune (sirolimus)</p> <p><i>Discussion and Q&As</i></p>	<p>Lisa Mathis, MD</p> <p>Lisa Jones, MD Medical Officer, Division of Psychiatry Products CDER</p> <p>Felicia Collins, MD, MPH, FAAP</p> <p>Evelyn Mentari, MD, MS Medical Officer, Division of Neurology Products CDER</p> <p>Rosemary Johann-Liang, MD, FAAP</p> <p>Andrew Mosholder, MD, MPH Epidemiologist, Division of Drug Risk Evaluation CDER</p> <p>Iris Masucci PharmD, BCPS CDER</p> <p>Alan Shapiro, MD, PhD, FAAP</p> <p>Alan Shapiro, MD, PhD, FAAP</p>
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3:45 Abbreviated Presentations and Updates to Committee:

Invanz (ertapenem)

Alan Shapiro, MD, PhD, FAAP

Gemzar (gemcitabine)

Alan Shapiro, MD, PhD, FAAP

Amaryl (glimepiride)

Lisa Mathis, MD

Novolog (insulin aspart recombinant)

Lisa Mathis, MD

Mobic (meloxicam)

Lisa Mathis, MD

Discussion and Q&As

Ditropan (oxbutynin) – Safety Update

Lisa Mathis, MD

Lipitor (atorvastatin) – Safety Update

Jean Temeck, MD
Medical Officer,
Pediatric and Maternal Health Staff
CDER

Zocor (simvastatin) – Safety Update

Jean Temeck, MD

Discussion and Q&As

4:30 Adjourn